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08/443, 982 05/18/95 DIXIT

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EXAMINER

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ART UNIT

PAPER NUMBER

1646

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/443,982	Applicant(s) Dixit et al.
	Examiner <i>David Romeo 7/10/98</i> David Romeo	Group Art Unit 1646

Responsive to communication(s) filed on May 26, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49, and 53-56 is/are pending in the application.

Of the above, claim(s) 53 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49, and 54-56 is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49, and 53-56 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on May 26, 1998 is/are objected to by the Examiner. *FOR EXAMINATION ONLY*

The proposed drawing correction, filed on May 26, 1998 is approved, disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 23, 24

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The finality of the last Office action is withdrawn in view of the reference(s) to Boldin et al. (3, cited by Applicants). Rejections based on the cited reference(s) follow.

2. The amendment filed 26 May 1998 has been entered. Claims 1-5, 21, 29, 30 and 37-56
5 are pending.

3. Applicant's election by original presentation with traverse of claims 1-6, 21, 23, 24, 29-32 and 37-52 in Paper No. 25 is acknowledged. The traversal is on the ground(s) that pursuant to the rule of rejoinder an applicant may present claims directed to the process of making and/or using the patentable product by way of amendment. This is not found persuasive because the
10 product has not been found patentable.

The requirement is still deemed proper and is therefore made FINAL.

4. Claim 53 remains withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 25.

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5. Claims 1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49, and 53-56 are pending. Claims 1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49, and 54-56 are being examined.

6. The objection to claims 2, 6, 21, 23, 24 and 46-52 because they depend from a non-elected base claim is withdrawn in part. The objection to claims 6, 21, 23, 24 and 46-52 is 5 withdrawn in view of Applicants' amendment. The objection to claim 2 is maintained.

7. The corrected or substitute drawings were received on 26 May 1998. These drawings are acceptable for examination purposes only.

8. Figure 2C is objected to under 37 CFR 1.83(a) because it fails to show the arrow indicated in the figure legend at page 4, lines 4-6. Correction is required.

10 9. The specification is objected to because of the following informalities: at page 4, line 1, "Figure 2B" should be --Figure 2C--. Appropriate correction is required.

Response to Arguments

10. The rejection of claims 2, 6, 21, 23, 24, 29-32, 44 and 46-52 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteins comprising SEQ ID NO:2,

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and analogs and fragments thereof, wherein said analogs have conservative amino acid substitutions, and wherein said analogs and fragments thereof have a specific functional activity, does not reasonably provide enablement for a FADD protein, is withdrawn in part. The rejection of claims 6, 21, 23, 24, 31, 32, 44 and 46-52 is withdrawn in view of Applicants' amendment.

5 The rejection of claims 2, 29 and 30 is maintained for reasons of record. Applicants have not presented any specific arguments regarding the rejection of claim 2. With respect to claims 29 and 30 Applicants argue that the claims have been amended in a sincere effort to place the claims in condition for allowance. Applicant's arguments have been fully considered but they are not persuasive. There are no structural limitations on "FADD" at lines 11 and 12 of claim 29 and at 10 lines 11 and 13 of claim 30, and the specification has not enabled the full scope of a FADD protein identified by name only for reasons of record in Paper no. 16, at page 5, lines 4-17. It is suggested that the claims recite --said FADD-- at lines 11 and 12 of claim 29 and at lines 11 and 13 of claim 30 in order to overcome this rejection of claims 29 and 30. However, note the rejection under 35 U.S.C. 112, second paragraph, regarding claims that recite "FADD".

15 11. The rejection of claim 32 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for AU1-N-FADD and FADDmt, does not reasonably provide enablement for fragments of FADD, is withdrawn in view of Applicants' amendment.

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12. The rejection of claims 29 and 30 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening for an agent that modulates the binding of FADD of SEQ ID NO:2 to the intracellular domain of the Fas receptor, does not reasonably provide enablement for a method of screening for an agent useful to modulate cellular function regulated by the Fas receptor pathway is withdrawn upon further consideration.

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13. The rejection of claims 21, 23, 31 and 32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of Applicants' amendment.

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14. The rejection of claims 1 to 5 and 31 to 32 under 35 U.S.C. 102(b) as being anticipated by Itoh (T, cited in previous Office action), is withdrawn in view of Applicants' amendment.

15. The rejection of claims 6, 50 and 51 under 35 U.S.C. 102(b) as being anticipated by Itoh et al. al. (U1), is withdrawn in view of Applicants' amendment.

16. The rejection of claims 21 and 23 under 35 U.S.C. 103(a) as being unpatentable over Itoh et al. al. (U1) in view of Berg et al. al. (A), is withdrawn in view of Applicants' amendment.

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17. The rejection of claims 3, 6, 21, 23, 41, 44, 45, 47-49 and 51 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in part. The rejection of claims 3, 6, 21, 23, 41, 44, 47-49 and 51 is withdrawn in view of Applicants' amendment. The rejection of claim 45 is maintained. Applicants argue that claim 45 finds support at page 4, line 4; in Figure 2B; and at page 9, lines 1-15. Applicant's arguments have been fully considered but they are not persuasive. This is a new matter rejection. Claim 45 recites the limitation "having conservative amino acid substitutions at amino acids 1 to 120 and 122 to 208". Support for this limitation cannot be found at the indicated locations in the specification.

18. The rejection of claims 1-6, 21, 23, 24, 29-32, and 37-52 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the recited FADD polypeptides that retain FADD activity, i.e. bind the cytoplasmic region of the Fas receptor or induce apoptosis in a cell, and compositions comprising said FADD, does not reasonably provide enablement for the recited FADD polypeptides and compositions without regard to the functional activity of the encompassed polypeptides is withdrawn in part. The rejection of claims 6, 24, 31, 32, 44, 47, and 50-52 is withdrawn in view of Applicants' amendment. The rejection of claims 1-5, 21,

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23, 29, 30, 37-43, 45, 46, 48 and 49 is maintained. The rejection of record is applied to claims 54-56. The rejection is recast as follows:

Claims 1-5, 21, 23, 29, 30, 37-43, 45, 46, 48, 49 and 54-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptides comprising SEQ ID NO:2, and analogs and fragments thereof, wherein said analogs have conservative amino acid substitutions, and wherein said analogs and fragments thereof either bind the cytoplasmic region of the Fas receptor or induce apoptosis in a cell, and compositions comprising said polypeptides and analogs and fragments thereof, does not reasonably provide enablement for the recited FADD polypeptides and compositions without regard to the functional activity of the encompassed polypeptides

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Applicants argue that the independent claims have been amended in accordance with the Office's suggestions. Applicant's arguments have been fully considered but they are not persuasive. Applicants have amended the claims to recite that polypeptides are "capable of" binding the cytoplasmic region of the Fas receptor or "capable of" inducing apoptosis in a cell or have the "ability to" perform these functions. The phrase "capable of" or "has the ability to" suggest other necessary but unnamed conditions that are required for the recited activity. It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. The claims do not recite a functional activity in

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a patentable sense. It is suggested that --binds-- and --induces-- replace "capable of binding" or "capable of inducing", respectively.

19. The rejection of claims 2, 37-44, 49 and 51 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which 5 applicant regards as the invention is withdrawn in view of Applicants' amendment.

20. The rejection of claims 2 and 46 under 35 U.S.C. 103(a) as being unpatentable over Itoh (T) as applied to claim 2 above, and further in view of Sambrook et al. (V2) is withdrawn in view of Applicants' amendment.

21. The rejection of claims 6 and 52 under 35 U.S.C. 103(a) as being unpatentable over Itoh 10 et al. al. (U1) as applied to claim 6 above, and further in view of Sambrook et al. (V2) is withdrawn in view of Applicants' amendment.

Newly Added Claim Rejections - 35 USC § 112

22. Claims 1, 3-5, 21, 37, 38, 39, 41, 42, 43, 46, 48, 49, 53-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly 15 claim the subject matter which applicant regards as the invention.

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Claims 1, 3-5, 21, 37, 38, 39, 41, 42, 43, 46, 48, 49, 53-56 are indefinite because they recite the term "FADD polypeptide". Because the instant specification does not identify that material element or combination of elements which is unique to and, therefore, definitive of "FADD polypeptide" an artisan cannot determine what additional or material functional 5 limitations are placed upon a claim by the presence of this element. It is suggested that the phrase --polypeptide-- be used instead.

23. Claims 1, 3-5, 37-43, 45, 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 Claims 1, 3-5, 37-43, 45, 54 and 55 are indefinite because the phrase "capable of" or "has the ability to" suggest other necessary but unnamed conditions that are required for the recited activity. It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. The claims do not recite a 15 functional activity in a patentable sense. The metes and bounds of the claim are not clearly set forth. It is suggested that --binds-- and --induces-- replace "capable of binding" or "capable of inducing", respectively.

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24. Claims 3 and 37-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 37-43 are indefinite because the claims recite specific amino acid sequences without reciting an appropriate sequence identifier, i.e. SEQ ID NO:. Whenever, particular amino acid residues in a sequence are referred to the reference is meaningless without the appropriate SEQ ID NO:.

25. Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 30 are indefinite because it is unclear in step "c)" what analysis is to take place. Furthermore, the method steps are directed to inhibiting the binding of FADD to the Fas receptor and it unclear if inhibiting binding is synonymous with the analysis or if some other process is to take place. It is suggested that step "c)" be deleted and that the claim preamble recite -- a method for screening for an agent that inhibits binding of the polypeptide of claim 54 to the Fas receptor.

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Newly Added Claim Rejections - 35 USC § 102

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

5 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

27. Claims 5, 46, 48, 55 and 56 are rejected under 35 U.S.C. 102(a) as being anticipated by Boldin et al. (3, cited by Applicants). Boldin et al. disclose a polypeptide fragment of the protein of claim 1 wherein the polypeptide consists of at least the N-terminal portion of the protein and an isolated FADD polypeptide fragment of the protein of claim 1 (see fragment 1-117 of MORT1 in Table 1, page 7796). Although Boldin et al. do not disclose that this fragment induces apoptosis in a suitable cell, it is reasonable to assume that this is an inherent property of the polypeptide fragment because the polypeptide fragment of Boldin et al. comprises the region of Applicants polypeptide that is required for inducing apoptosis (See Figure 8B of the instant application, fragments AU1-N-FADD and AU1-NFD-2). Boldin et al. also disclose a fusion protein comprising the polypeptide fragment, a composition comprising the polypeptide fragment and a carrier and the polypeptide fragment which has been recombinantly produced *in vitro* and isolated from a host cell (page 7795, column 2, full paragraphs 1-3).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, 5 Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the Examiner at (703) 308-0294.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

DSR *DSR*
July 10, 1998